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#32

J. Trevor Lumb  
Pfizer Inc.  
Patent Department  
Eastern Point Road  
Groton, CT 06340

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,517,359

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,517,359 issued May 14, 1985, which claims the human drug product Zithromax, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 1,267 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of January 27, 1993. The January 27, 1993, notice corrected an original notice of the regulatory review period published in the Federal Register of March 31, 1992. Under 35 USC § 156 (c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (1,795) + 570 \\ &= 1,468 \text{ days}\end{aligned}$$

Since the regulatory review period began October 28, 1984, before the patent issue date, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. The period of time from the start of the regulatory review period on October 28, 1984, up to the issuance of the patent on May 14, 1985, is 197 days. This period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period:  $1,992 - 197 = 1,795$  days. No determination of a lack of due diligence was made.

The 14 year exception of 35 USC § 156 (c) (3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured after the date of approval of the approved product (November 1, 1991) when added to the period of extension calculated above (1,468 days) cannot exceed fourteen years. The period of extension is thus limited to November 1, 2005, by operation of 35 USC § 156 (c) (3). Since the patent term of seventeen years (35 USC § 154) would expire on May 14, 2002, the period of extension is the number of days to extend the term of the patent from its expiration date to and including November 1, 2005, or 1,267 days.

The limitations of 35 USC § 156 (g) (6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136 (a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,517,359 a certificate of extension, under seal, for a period of 1,267 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,517,359
Granted:	May 14, 1985
Applicant:	Gabrijela Kobrehel et al
Owner of Record:	Pliva Pharmaceutical, Chemical, Food and Cosmetic Industry
Title:	11 - METHYL - 11 - AZA - 4 - 0 - CLADINOSYL - 6 - 0 - DESOSAMINYL - 15 - ETHYL - 7,13,14 - TRIHYDROXY - 3,5,7,9,12,14 - HEXAMETHYL - OXACYCLOPENTADECANE - 2 - ONE AND DERIVATIVES THEREOF
Classification:	536/7.4
Product Trade Name:	Zithromax
Term Extended:	1,267 days

*C. E. Van Horn*

Charles E. Van Horn  
Patent Policy & Projects Administrator  
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 11-44  
Rockville, MD 20857

RE: Zithromax  
FDA Docket No.: 92E - 0027